7-12-91

Note to Frank Sanders, FHB, RD

Subject: Chlorothalonil and Nustar (flusilazole) Contamination of Benomyl Formulations

I'm attaching Dr. Schmitt's memo regarding Chem Branch's opinion of the significance of benomyl's contamination. Using Schmitt's worst-case ratio of contamination and similar deposition and dissipation rates rough estimates of exposure and thus risk can be made for chlorothalonil and Nustar residues appearing on benomyl treated crops.

Estimates of exposure can be made by multiplying the TMRC for benomyl (0.056 mg/kg/day) times the contamination ratio of 6×10^{-4} for chlorothalonil or 8×10^{-4} for Nustar. The resulting dietary lifetime exposure for 100% of crops treated are 3.4×10^{-5} mg/kg/day for chlorothalonil and 4.5×10^{-5} mg/kg/day for Nustar. For chlorothalonil (a B_2 carcinogen with a Q_1* potency factor of 0.011) the most sensitive indicator of risk is its cancer potential. The lifetime cancer risk (100% crop treated) is $(3.4 \times 10^{-5}) \times (0.011)$ or 4×10^{-7} for chlorothalonil.

Nustar, due to the lack of an MTD, is being retested for cancer. One year interim data for female rats showed an increase in urinary bladder transitional cell carcinomas in the high dose group. The complete study has not been sent in nor reviewed but is likely that a Peer Review will be needed. Currently there is an ADI (RfD) available for Nustar based on a NOEL of 0.2 mg/kg/day in a dog study and a safety factor of 300. When the exposure estimate of 4.5×10^{-5} is compared to the RfD of 7×10^{-4}, only 6.5% of the RfD is used by Nustar contamination of benomyl.

Attachment
cc: Caswell file (Benonyl)
Penelope Fenner-Crisp
Richard Schmitt

7/12/91

July 11, 1991

Subject: Contamination of Benomyl Formulations

Benlate DF (50% benomyl) has been reported to have been contaminated with atrazine, chlorothalonil and Nustar. The atrazine contamination of benlate was reported as 100 ppm in 1989 and 2-5 ppm this year. The chlorothalonil contamination of benlate was reported as ranging from < 10 ppm to 300 ppm. The Nustar (flusilazole) contamination of benlate ranged from < 2 ppm to 422 ppm.

If the contamination level is 100 ppm, the contaminant/benomyl ratio is:

$$100 \text{ ppm}/500{,}000 \text{ ppm} = 0.0002 \ (2 \times 10^{-4})$$

Other contaminate ratios can be estimated in a similar manner.

If one assumes similar deposition and dissipation for the contaminants and benomyl residues, the maximum residues of the contaminant on crops can be estimated by multiplying the contaminant/benomyl ratio times the tolerance levels for benomyl.

For example, if the atrazine/benomyl ratio is 0.00001 (i. e., 5 ppm atrazine in Benlate) and the grape tolerance for benomyl is 10 ppm, maximum atrazine residues in grapes are estimated to be 0.00001 times 10 ppm = 0.0001 ppm. The following table shows estimated contaminant residues in some representative crops assuming 5 or 100 ppm atrazine contamination, 300 ppm chlorothalonil contamination and 400 ppm Nustar contamination.

CONTAMINANT RESIDUE LEVELS

CROP	BENOMYL TOLERANCE (ppm)	5 ppm ATRAZINE (ppm)	100 ppm ATRAZINE (ppm)	300 ppm Chlorothalonil (ppm)	400 ppm Nustar (ppm)
BEAN FORAGE	50	0.0005	0.01	0.03	0.04
PINEAPPLES	35	0.00035	0.007	0.021	0.028
GRAPES	10	0.0001	0.002	0.006	0.008
CUCUMBERS	1	0.000001	0.0002	0.0006	0.0008

Considering that the detection limit for atrazine is in the 0.02-0.05 ppm range, it is very unlikely that detectable residues of atrazine will be found on crops treated with Benlate containing 5 ppm of atrazine (the contamination level found this year). If the contamination level rises to 100 ppm, it is possible that atrazine residues could approach the detection limit in those crops having the highest benomyl tolerances.

For chlorothalonil, the detection limit is 0.01 ppm. It is possible that detectable residues of chlorothalonil will be found on crops such as bean forage or pineapple treated with Benlate containing 300 ppm chlorothalonil. In fact, any crop with a benomyl tolerance of 15 ppm or greater could have detectable residues of chlorothalonil if treated with benlate containing 300 ppm chlorothalonil.

For Nustar, the detection limit is 0.005 to 0.01 ppm. Crops having benomyl tolerances at 10 ppm or higher that are treated with Benlate containing 400 ppm Nustar contaminant may show detectable residues of Nustar. In the above table, bean forage and pineapples could all show detectable residues of Nustar.

R D Schmitt